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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,362	01/23/2004	Mark William Bodmer	674525-2008	7568

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EXAMINER	
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ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/763,362	**Applicant(s)** BODMER ET AL.	
	Examiner PHUONG HUYNH	**Art Unit** 1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 October 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *5* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None* .
   Claim(s) objected to: *None*.
   Claim(s) rejected: *1,18,29,31 and 37*.
   Claim(s) withdrawn from consideration: *30,32 and 33*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Phuong Huynh/
Primary Examiner, Art Unit 1644

Continuation of 11. does NOT place the application in condition for allowance because:

The new matter rejection of Claims 1, 18, 29 and 31 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed October 27, 2010 have been fully considered but are not found persuasive. Applicant's position is that the specification recites that the first sequence may comprise "a polypeptide that is capable of binding to a MHC class II molecule." Specification, p. 12, 11.17-19. The specification also indicates the first sequence may "take the form of an antibody to an APC surface molecule." Id., p.13, 11.12-13. Given that a MHC class II molecule is an APC surface molecule, the skilled artisan would recognize that the specification supports an antibody (or binding fragment thereof) that binds to an MHC class II molecule.

Contrary to applicants' assertion that that the specification indicates the first sequence may take the form of antibody to an APC surface molecule such as MHC class II molecule, the paragraph at page 12 reproduces below:
"The first sequence is capable of targeting a second sequence to an APC for presentation to a TCR. In a preferred embodiment the first sequence comprises a polypeptide that is capable of binding to a MHC class II molecule. Preferably the first sequence is or is derived from a superantigen and comprises the MHC class II molecule binding domain thereof. Preferably the first sequence does not include the TCR binding domain of the superantigen.", see page 12, lines 16-21.

Said paragraph discloses that the first sequence that binds to MHC class II molecule is a superantigen, not an antibody as argued. Furthermore, the specification at page 13 discloses "In another embodiment the first sequence comprises a polypeptide which is capable of binding to another APC surface molecule. Such APC molecules include: CD205 (DEC205), CD204 (Scavenger receptor), CD14, CD206 (Mannose receptor), TLRs, Langerin (CD207), DC-SIGN (CD209), Fc), receptor 1 (CD64) and Fc), receptor 2 (CD32), CD68, CD83, CD33, CD54 and BDCA-2,3,4."

"It will be appreciated that the first sequence may therefore take the form of an antibody to an APC surface molecule. In a preferred embodiment the antibody is generated against the APC extracellular domain of the APC surface molecule, or a fragment thereof. The production of antibodies is described in for example Kohler and Milstein (1975) Nature 256:495-497." Again, there is no mentioned of MHC molecule and antibody that binds to such.

Finally, the claims and the specification as originally filed fail to provide written support for the claimed limitation of antibody or binding fragment thereof that binds to MHC class II molecule other than superantigen TSS1. No amendment shall introduce new matter into the claims. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). For these reasons, the rejection is maintained.

Claims 1, 18, 29, 31 and 37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No 7,030,228 B 1 (filed November 15, 2000; PTO 892) in view of US application 2005/0137130 A1 (filed May 14, 2004; PTO 892).

Applicants' arguments filed October 27, 2010 have been fully considered but are not found persuasive. Applicant's position is that based on the teachings of the ' 130 publication, one of ordinary skill in the art would understand human Delta 1 to be used in the ' 130 publication as an inhibitor of Notch signaling. See, e.g., ' 130 publication, 0066-67, 0070-71, 0094,1099-1102. However, this teaches away from the instant claims that recite that the second sequence or the Notch ligand (or a fragment thereof) retains Notch signaling activity. Thus, the '130 publication teaches away from the claimed invention. In addition, the skilled artisan could not have predicted, based on the teachings in the '130 publication, that the second sequence or Notch ligand of the invention would retain Notch signaling activity.

In response, the notch ligand of the '130 publication comprises the amino acid sequence of SEQ ID NO: 51, which is identical to the claimed SEQ ID NO: 40 in the second sequence in the fusion protein. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. In this case, if applicant's Notch ligand retains Notch signaling activity, so is the reference notch ligand which comprises the exact amino acid sequence. If the reference Notch ligand does not retain Notch singlaing activity, neither is applicants' Notch ligand.

With respect to the argument that the ' 130 publication teach inhibitor of Notch signaling, while the '130 publication teaches the reference fragment has inhibitory activity of Notch signaling, the full-length sequence of SEQ ID NO: 51 still retains Notch signaling activity because the term "or" is recited in claim 1. For these reasons, the rejection is maintained.

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